

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO Box 1450 Alexasotra, Virginia 22313-1450 www.repto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,369	06/23/2005	Zen-ichi Terashita	10525.009	2737
22852 7590 10/22/2008 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON. DC 20001-4413			EXAMINER	
			STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
		1626		
			MAIL DATE 10/27/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Application No. Applicant(s) 10/540,369 TERASHITA ET AL. Office Action Summary Examiner Art Unit Laura L. Stockton, Ph.D. 1626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 16 July 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-14 and 16-22 is/are pending in the application. 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 14 and 16-22 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Imformation Disclosure Statement(s) (PTC/G5/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_.

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

Art Unit: 1626

#### DETAILED ACTION

Claims 1-14 and 16-22 are pending in the application.

#### Election/Restrictions

Applicant's election without traverse of Group III in the reply filed on March 20, 2008 was acknowledged in the previous Office Action. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Subject matter not embraced by elected Group III and Claims 1-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on March 20, 2008.

Art Unit: 1626

Rejections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the R<sup>1</sup> variable, the X variable, the A variable substituent, the R<sup>2</sup> variable and the R<sup>3</sup> variable are not adequately defined so that the metes and bounds of the claim can be ascertained. Therefore, claim 16 is indefinite.

Application/Control Number: 10/540,369
Art Unit: 1626

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 16-22 are rejected under 35
U.S.C. 103(a) as being unpatentable over Momose et al.
{U.S. Pat. 6,251,926}.

# Determination of the scope and content of the prior art (MPEP \$2141.01)

Applicant claims a method of inhibiting a body weight gain in a mammal comprising administering a compound of formula (I). Momose et al. (see entire document) teach a method for treating obesity (column 22, lines 39-43 and 61-63) by administering combinations of agents/drugs (column 23, lines 6-26) for treating a disease such as obesity comprising an

Application/Control Number: 10/540,369
Art Unit: 1626

insulin sensitivity enhancing agent (i.e., pioglitazone hydrochloride - column 23, lines 31-33), and any other two kinds of agents (column 24, lines 54-67 and column 25, lines 1-2) such as an angiotension II antagonist {i.e., Candesartan (a compound of instant formula (I) - column 23, lines 63-65} and an antiobesity agent (i.e., dexfenfluramine - column 23, line 67).

### Ascertainment of the difference between the prior art and the claims (MPEP \$2141.02)

The difference between the method of the prior art and the method instantly claimed is that the drugs/agents utilized in the instant claimed method of use are generically taught in the prior art.

## Finding of prima facie obviousness--rational and motivation (MPEP \$2142-2413)

The indiscriminate selection of "some" among "many" is prima facie obvious, <u>In re Lemin</u>, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the combination of drugs/agents derives from the

Application/Control Number: 10/540,369 Page 6

Art Unit: 1626

expectation that the combinations of drugs/agents would be beneficial in treating a disease (e.g., treating obesity).

One skilled in the art would thus be motivated to prepare combinations of drugs/agents embraced by the prior art to arrive at the instant claimed method of use with the expectation of obtaining additional beneficial products which would be useful in treating obesity. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP

Application/Control Number: 10/540,369

\$706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains subject matter not embraced by elected Group III and Claims 1-13 drawn to

Application/Control Number: 10/540,369

an invention nonelected without traverse in the reply filed on March 20, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/540,369 Page 9
Art Unit: 1626

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton, Ph.D.
Primary Examiner, Art Unit 1626
Work Group 1620
Technology Center 1600

November 1, 2008